K063626

FEB 8 2007

Cosmetic Dental Materials

CDM Inc.
812 Water Ave NE
Albany OR 97321
Phone: 541-928-4444
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510 (K) Summary

Submitter Name:	CDM Inc.
Submitter Address:	812 Water St NE Albany OR 97321
Submitter Telephone: Submitter Facsimile:	541-928-4444 541-928-2444
Contact Person:	Bob Bowers Chief Operating Officer
Date Summary Prepared:	October 23, 2006

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR.807.92.

9.1 SUBMITTER INFORMATION

a. Company Name:	CDM Inc.
b. Company Address:	812 Water St NE Albany OR 97321
c. Company Telephone: Company Facsimile:	541-928-4444 541-928-2444
d. Contact Person:	Bob Bowers Chief Operating Officer
e. Date Summary Prepared:	October 23, 2006

9.2 DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	DuraFlex
b. Classification Name:	Denture relining, repairing or rebasing resin. 21 CFR 872.3760

9.3 IDENTIFICATION OF PREDICATE DEVICES

The DuraFlex material is a thermoplastic resin used to fabricate partial or full removable dentures, as well as occlusal splints and night guards. This material is substantially equivalent to Lucitone FRS Flexible Dental Resin manufactured by Dentsply International. This material is commercially available in the United States.

9.4 DEVICE DESCRIPTION

The DuraFlex material is a thermoplastic resin that is used to fabricate dental prostheses. The resin is used in an injection molding or pressing device to fabricate the prostheses.

9.5 SUBSTANTIAL EQUIVALENCE

The DuraFlex thermoplastic resin is substantial equivalent to Lucitone FRS Flexible Dental Resin. The fundamental characteristics are similar: the DuraFlex thermoplastic resin is similar in design, function, physical properties and intended use to the predicate device.

9.6 INDICATIONS FOR USE

The DuraFlex material is a thermoplastic resin intended for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

9.7 TECHNOLOGICAL CHARACTERISTICS

Both the DuraFlex and the predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Bowers
Chief Operating Officer
CDM, Incorporated
812 Water Avenue, NE
Albany, Oregon 97321

FEB 8 2007

Re: K063626
Trade/Device Name: DuraFlex™
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: January 29, 2007
Received: February 05, 2007

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

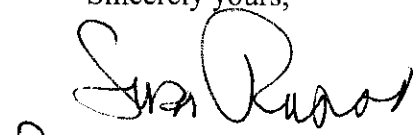
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K063626

Device Name DuraFlex

Indications for use:

The DuraFlex thermoplastic resin is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.
Dental Device Class II, 872.3760

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Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the counter ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K063626